

**IN THE UNITED STATES DISTRICT COURT  
FOR DISTRICT OF NEW JERSEY**

**ARLENE SECHTIN, on behalf of herself )  
and all others similarly situated, )**

**Plaintiff, )**

**vs. )**

**REGENERATION TECHNOLOGIES, )  
INC., AND BIOMEDICAL TISSUE )  
SERVICES, LTD., )**

**Defendants. )**

**CIVIL ACTION NO.:  
JURY TRIAL DEMANDED**

**CLASS ACTION COMPLAINT**

Plaintiff Arlene Sechtin, on behalf of herself and all others similarly situated, residing at 110 N. Richards Ave., Ventnor City, New Jersey, 08406, by her attorneys, CUNEO, POGUST & MASON, LLP; CUNEO, GILBERT & LaDUCA, LLP; THE MASON LAW FIRM; and LEVIN, FISHBEIN, SEDRAN, & BERMAN, as and for the Verified Complaint herein allege upon information and belief the following

**NATURE OF ACTION**

1. Plaintiff Arlen Sechtin brings this Class Action Complaint on behalf of herself and all other similarly situated as human tissue and transplant patients, recipients, users, consumers, and benefactors of tissue and tissue related-services against Defendants Regeneration Technologies, Inc. ("RTIX") and Biomedical Tissue Services, Ltd ("BTS") for battery, intentional and negligent infliction of emotional harm, violation of New Jersey's Consumer Fraud Act, and violation of New Jersey's Product Liability Act.

2. Defendant BTS illicitly and unlawfully harvested, collected, extracted, and obtained body parts and other human tissue from corpses that were obtained, provided and otherwise facilitated by various funeral homes.

3. Defendant BTS failed to properly test, assess, evaluate, and screen such human tissues for various infectious diseases prior to distributing, shipping, and sending said human tissues to numerous tissue processors through out the United States including RTIX.

4. Defendant RTIX used, employed, and otherwise utilized such human tissue supplied by BTS for purposes of providing medical grafts, allografts, bone implants and pasting, dental implants, orthopedic and other medical surgical reconstructive procedures.

5. Defendant RTIX failed to properly monitor, assess, evaluate and employ an adequate BioCleanse® and/or similar process for such human tissues received in the chain of commerce from BTS to thoroughly screen for infectious diseases and was negligent and reckless in insuring the proper safety, sterilization, and other regulatory standards thereby subjecting tissue recipients such as Plaintiff and all others similarly situated to severe emotional distress and physical harms.

6. Defendants RTIX and BTS are liable to Plaintiff and all other similarly situated Plaintiffs for physical and emotional harms and damages as a result of Defendants said reckless, wrongful, unlawful, outrageous, and negligent conduct.

#### **JURISDICTION AND VENUE**

7. Jurisdiction is premised upon diversity of citizenship pursuant to 28 U.S.C. §1332(d) in that Plaintiff a class member is citizen of New Jersey and Defendants

are citizens of Florida and New Jersey and the amount in controversy greatly exceeds Five Million Dollars (\$5,000,000.00).

8. Venue is proper in this district pursuant to 28 U.S.C. §1961, et. seq., as many of the acts complained of herein, including but not limited to the various predicate acts of battery, intentional and negligent infliction of emotional distress, and violation of consumer protection and fraud statutes, and the consequences thereof, occurred within New Jersey and/or were known or intended by Defendants to occur in or have consequences in New Jersey.

### **PARTIES**

9. At all time relevant herein, Plaintiff Arlene Sechtin ("Arlene") was a resident of the State of New Jersey, and currently resides at 110 N. Richards Avenue, Ventor City, New Jersey, 08406.

10. Defendant RTIX is a Delaware corporation with its principal office and place of business at 11621 Research Circle, Alachua, Florida, 32615. Defendant RTIX at all times relevant developed, produced, sold, and distributed tissue related products including but not limited to, medical grafts, allografts, bone implants, bone paste, dental implants, and other products used in orthopedic and medical surgical reconstructive procedures, throughout the United States and the world and does substantial and continuing business in the State of New Jersey. Upon information and belief, RTIX is licensed and registered to do business in New Jersey and obtained the benefits of the laws of New Jersey and profited from New Jersey commerce.

11. BTS is a New Jersey corporation and with its principal office and places of business at 260 Columbia Avenue, Suite # 1, Fort Lee, New Jersey, 07024 and

harvests and extracts human bones, skin, and tendons and then distributes said extractions throughout the United States and does substantial and continuing business in the State of New Jersey.

### **CLASS ALLEGATIONS**

12. Plaintiff seeks to bring this case as a class action, under Federal Rule of Civil Procedure 23 *et. seq.*, on behalf of herself and all others similarly situated in the United States as members of proposed class, defined as follows: All persons, consumers, recipients, benefactors, of human tissue products harvested, distributed, and supplied by and adversely affected and harmed by the wrongful acts of Defendants RTIX and BTS.

### **NUMEROSITY**

13. The wrongful acts and conduct by Defendants RTIX and BTS as alleged herein, has harmed and continues to harm persons throughout the United States. The members of the Class are so numerous that joinder of all members is impracticable.

14. The exact numbers of Class Members is unknown as such information is in the exclusive control of Defendants. However, due to the nature of the trade and commerce involved, Plaintiff believes the class consists of thousands of recipients, recipients, users, consumers, and benefactors of said tissue and tissue services throughout the United States from early 2004 to September 2005, making joinder of Class Members impracticable.

### **COMMON QUESTIONS OF LAW AND FACT**

15. Common questions of law and fact affect the right of each Class Member and a common relief by way of damages is sought for the Plaintiff Class Members.

16. The harm that Defendants have caused or could cause is substantially uniform with respect to Class Members. Common questions of law and fact that affect the Class Members include but are not limited to:

a. Whether Defendants intentionally, recklessly, and negligently placed illicitly and unlawfully obtained human tissues at risk not screened or tested for infectious disease into the stream of commerce;

b. Whether the Defendants failed to adhere to the proper standard of care in harvesting, developing, producing, and distributing human tissues, to be used in medical grafts, allografts, bone implants and pasting, dental implants, and orthopedic and medical surgical reconstructive procedures throughout the United States;

c. Whether the Defendants failed to prevent the harm and damages occurring to patients, recipients, users and benefactors of said tissue as a result of being exposed to such human tissues and the risk of infectious diseases;

d. Whether the Defendants violated New Jersey's Consumer Fraud Act N.J.S.A. 56:8-1 *et. seq.* or similar statutes in effect in other jurisdictions throughout the United States; and

e. Whether the Defendants violated New Jersey's Product Liability Act N.J.S.A. § 2A: 58C-1; 58C-8) or similar statutes in effect in other jurisdictions throughout the United States; and

f. Whether the Members of the Class sustained harms and damages and if so, the proper measure of such damages.

### **TYPICALITY**

17. The claims and defenses of the Plaintiff as the representative Plaintiff are typical of the claims and defenses of the Class.

### **ADEQUACY OF REPRESENTATION**

18. Plaintiff Sechtin as the representative Plaintiff, will fairly and adequately assert and protect the interests of the Class:

a. Plaintiff Sechtin has hired Attorneys who are experienced in prosecuting class actions claims and will adequately represent the interests of the Class; and

b. Plaintiff Sechtin has no conflict of interest that will interfere with the maintenance of this class action.

### **SUPERIORITY**

19. A class action provides a fair and efficient method for the adjudication of controversy for the following reasons:

a. The common questions of law and fact set forth in Paragraph 16 predominate over any questions affecting only individual class members;

b. The Class is so numerous as to make joinder impossible. However, the Class is not so numerous as to create manageability problems. There are no unusual legal or factual issues which would create any manageability problems.

c. Prosecution of a separate action by individual members of the class would create a risk of inconsistent and varying adjudications against Defendants when confronted with incompatible standards of conduct;

d. Adjudications with respect to individual members of the class could, as a practical matter, be dispositive of any interest of other members not parties to such adjudications, or substantially impair their ability to protect their interests.

e. Upon information and belief, Defendants are responsible for the wrongful acts resulting in harm and damage to Plaintiff in New Jersey, making this forum appropriate for the litigation of the claims of the entire Class; and

f. The claims of the individual class members are small in relation to the expenses of litigation, making a class action the only procedure in which Class Members can, as a practical matter, recover. However, the claims of individual class members are large enough to justify the expense and effort in maintaining a class action.

#### **COMMON FACTUAL ALLEGATIONS**

20. Upon information and belief, prior to November 2005, Defendant BTS entered into a illicitly-designed and organized commercial enterprise with various funeral homes to harvest and extract from corpses, various human bone, skin, tendons, and other human tissue.

21. Upon information and belief, the various human bone, skin, tendons, and other human tissue illicitly extracted by Defendant BTS was never properly screened, tested, processed, or evaluated for certain infectious diseases such as HIV, hepatitis, syphilis, and other viral infections.

22. Under federal rules and regulations, Defendant BTS was under a duty and legal obligation to screen such extracted human bone, skin, tendons, and other human

tissue for such infectious diseases and to insure said extractions met federal regulatory donor eligibility requirements.

23. Despite such federal rules and regulations and upon information and belief, BTS proceeded to distribute, sell, and supply such extracted human bone, skin, tendons, and other human tissue to tissue processors throughout the United States.

24. Upon information and belief, BTS distributed, sold, and supplied said extracted human bone, skin, tendons, and other human tissue to various tissue processors from early 2004 to September of 2005.

25. Upon information and belief, prior to November 2005, BTS distributed, sold, and supplied extracted human bone, skin, tendons, and other human tissue to RTIX and that such extracted materials were never properly screened or tested for infectious diseases as required by the FDA.

26. Upon information and belief, prior to November 2005, RTIX upon receipt of said extracted human bone, skin, tendons, and other human tissue from BTS, then processed said extractions for purposes of medical grafts, allografts, bone implants, bone paste, dental implants, orthopedic and other medical surgical reconstructive procedures

27. Prior to November 2005 and upon information and belief, RTIX failed to properly screen, test, process, or evaluate such extractions for certain infectious diseases such as HIV, hepatitis, syphilis, and other viral infections.

28. Despite this and upon information and belief, RTIX continued to process said extractions received from BTS, including but not limited to human bone, for the purpose of creating bone paste which was later send to various health care providers, including Plaintiff's health care provider.



29. On March 31, 2005, Plaintiff underwent a surgical procedure in her back and spine to remedy degenerative disc-related problems and severe back-pain. The surgical procedure consisted of fusing various rods and discs to Plaintiff's spine and included the use of bone paste to adhere such spinal hardware to her spine and facilitate bone growth.

30. Upon information and belief, all others similarly situated to Plaintiff also received various orthopedic and other medical surgeries which utilized, employed, and incorporated the use of extracted human bone, skin, tendons, and other human tissue from BTS and RTIX, including but not limited to the use of bone paste.

31. Upon information and belief, Plaintiff's physician on March 31, 2005, utilized, employed, and incorporated extracted bone paste and other tissues distributed in the chain of commerce by BTS and RTIX.

32. On October 26, 2005 the FDA commenced an investigation into human tissue recovered by BTS and sent to tissue processors such as RTIX. As the FDA stated, "because of the potential lack of proper screening of the tissue donors, some recipients of the tissues may be at increased risk of infections that could potentially be transmitted through tissues."

33. As a result of the FDA's investigation, RTIX was required to recall all unused tissue remaining in inventory and to promptly notify implanting physicians, including Plaintiff's physician, of the risks of infectious disease among patients that may have received such products.

34. On November 18, 2005 Plaintiff was contacted by her physician and informed that the FDA had issued a recall to one of the products utilized in her March 31,

2005 spinal surgery. Upon her physician's request, Plaintiff was required to meet with him to discuss the recall.

35. Plaintiff's physician later confirmed that she had been the recipient of processed human tissue and bone paste distributed, supplied, and provided by Defendants.

36. Plaintiff was required to undergo additional testing for infectious diseases such as HIV, hepatitis, syphilis, and other viral infections. Plaintiff will still require additional testing, monitoring, and medical treatment as a result of Defendant's wrongful conduct.

37. As a result of Defendants' wrongful conduct, Plaintiff and all others similarly situated have suffered severe emotional distress and physical harm.

#### **COUNT I – BATTERY**

38. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

39. Defendants intentionally, willfully, recklessly, and negligently put Plaintiff Arlene and all others similarly situated in reasonable fear of a harmful or offensive contact with her body and the Defendants intended to cause a harmful or offensive contact with Plaintiff Arlene which directly and/or indirectly resulted in a harmful and offensive contact with her body as set forth under the Restatement (Second) of Torts, § (1965).

40. Plaintiff Arlene has in the past been required and may in the future continue to be required to submit to medical examinations; she sustained other injuries to internal system; she sustained other psychological injuries, the full extent of which have

yet to be determined; she has in the past required and may in the future continue to require medicines, medical care and treatment; she has in the past and may in the future continue to be compelled to expend monies and incur obligations for such medical care and treatment; she has in the past suffered and may in the future continue to suffer agonizing aches, pains and mental anguish; she has in the past been and may in the future continue to be disabled from performing her usual duties, occupations and avocations, all to her great detriment and loss; and she has suffered a breach of her right to essential human dignity as a result of the failure of Defendants to conduct such tissue extracting and distributing procedures in accordance with standards governing the proper standard of care.

41. As a direct and proximate result of Defendant's actions, as set forth above, Plaintiff has in the past been and may in the future continue to be compelled to expend monies and incur obligations for her medical care and treatment; Plaintiff has also incurred and may hereafter continue to incur other financial expenses or losses which do or may exceed amounts which Plaintiff may otherwise be entitled to recover.

42. Plaintiff Arlene has sustained and makes claims for pain and suffering, loss of physical function, permanent physical, mental, dignitary and psychological injuries, humiliation and embarrassment, loss of life's pleasures, loss of earning capacity, and any and all the damages to which she is or may be entitled under the law of New Jersey.

*WHEREFORE*, Plaintiff Arlene Sechtin, on behalf of herself and all others similarly situated, claim of Defendants, compensatory damages, punitive damages, interest and allowable costs of suit.

## **COUNT II – INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS**

43. Plaintiff incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

44. Plaintiff suffered severe emotional distress, which was the direct and proximate result of Defendants extreme, outrageous, intentional, willful, and reckless conduct in harvesting, extracting, processing, testing, developing, inspecting, producing, packaging, labeling, advertising, marketing, promoting, distributing, and/or selling various human tissue and tissue related products and/or services.

45. Plaintiff suffered severe emotional distress, which was the direct and proximate result of Defendants extreme, outrageous, intentional, willful, and reckless conduct in failing to reviewing donor's medical history and other factors, physically assessing the donor and source of tissue, and testing for relevant communicable diseases.

46. As a result of the foregoing, Defendants are liable to Plaintiff and all others similarly situated.

*WHEREFORE*, Plaintiff Arlene Sechtin, on behalf of herself and all others similarly situated, claim of Defendants, compensatory damages, punitive damages, interest and allowable costs of suit.

## **COUNT III – NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS**

47. Plaintiff incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

48. Plaintiff suffered severe emotional distress, which was the direct and proximate result of Defendants negligent conduct in harvesting, extracting, processing, testing, developing, inspecting, producing, packaging, labeling, advertising, marketing,

promoting, distributing, and/or selling various human tissue and tissue related products and/or services.

49. Plaintiff suffered severe emotional distress, which was the direct and proximate result of Defendants negligent conduct in failing to reviewing donor's medical history and other factors, physically assessing the donor and source of tissue, and testing for relevant communicable diseases.

50. As a result of the foregoing, Defendants are liable to Plaintiff and all others similarly situated.

*WHEREFORE*, Plaintiff Arlene Sechtin, on behalf of herself and all others similarly situated, claim of Defendants, compensatory damages, punitive damages, interest and allowable costs of suit.

**COUNT IV - VIOLATION OF NEW JERSEY'S CONSUMER FRAUD ACT**  
(*N.J. Stat. Ann. § 56:8-1 et. seq.*)

51. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

52. Defendants are merchants with respect to its supplying, selling, and distributing of human tissue, including but not limited to processed human tissue in the form of bone paste and medical grafting material

53. Defendants knowingly committed unfair and deceptive trade practices in its harvesting, extracting, processing, testing, developing, inspecting, producing, packaging, labeling, advertising, marketing, promoting, distributing, and/or selling various human tissue products and tissue processing related services.

54. Defendants knowingly committed unfair and deceptive trade practices in failing to reviewing various donors' medical history and other factors, physically assessing the donor and source of tissue, and testing for relevant communicable diseases.

55. When Defendants were harvesting, extracting, processing, testing, developing, inspecting, producing, packaging, labeling, advertising, marketing, promoting, distributing, and/or selling various human tissue products and tissue processing related services, Defendants knew or reasonably should have known that some human tissues were at risk of infectious diseases and subjecting individuals to harms related to HIV, hepatitis, syphilis, and other viral infections.

56. At no time did Defendants inform the FDA or the general public of its knowledge concerning the dangers of some adults who were being distributed such human tissues for various orthopedic and surgical procedures, including but not limited to grafts and bone paste.

57. Defendants also failed to give adequate warnings regarding the use and potential problems with such processed human tissue and tissue related services.

58. Defendants' actions complained of herein occurred in the conduct of trade or commerce, and all of the conduct alleged herein occurred in the course of Defendants' business.

*WHEREFORE*, Plaintiff Arlene Sechtin, on behalf of herself and all others similarly situated, claim of Defendants, compensatory damages, punitive damages, interest and allowable costs of suit.

**COUNT V - VIOLATION OF NEW JERSEY'S PRODUCTS LIABILITY ACT**

*(N.J.S.A. § 2A: 58C-1; 58C-8)*

59. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

60. RTIX is a corporation which tests, processes, distributes, supplies, and sells, certain processed human tissue throughout the United States and the world and does substantial and continuing business in the State of New Jersey. BTS is a corporation that extracts, harvests, tests, screens, processes, distributes, supplies, and sells certain human bones, skin, tendons, and other human tissue.

61. RTIX and BTS failed to inform the FDA and the public at large of the results that processed tissue supplied to various health care providers was at an increased risk of containing infectious diseases and other health related harms.

62. RTIX and BTS was careless, negligent, breached its duties and obligations owed to plaintiff's decedent by various sections of the New Jersey's Product Liability Act, N.J.S.A. § 2A: 58C-1; 58C-8, and is liable for causing injuries to plaintiff for the following reasons:

- a) selling a product in a defective condition;
- b) selling a product which was unreasonably dangerous to the user;
- c) failing to supply adequate warnings with the product;
- c) failing to provide accurate and truthful instructions to be followed with regard to the prescribing of this product;
- d) selling a product wherein it was foreseeable that someone would be injured upon the human tissue being utilized, employed, and/or transplanted;
- e) selling a product which was not safe for its intended use;

- f) selling a product which was lacking of one or more elements necessary to make it safe for its intended use;
- g) manufacturing a product which was defective and which could cause injury to the user;
- i) designing a product which was defective and which could cause injury to the user;
- j) distributing a product which was defective and could cause injuries to a user;
- k) failing to see that ultimate users were advised of the dangers of said product;
- l) failing to exercise reasonable care in the design of this product;
- m) failing to exercise reasonable care in the marketing of this product;
- n) failing to adequately and properly test said product;
- o) failing to use reasonable care under the circumstances;
- q) delivering a product which was defective and could cause injury to the user;
- bb) producing a product which was defective and could cause injury to the user;
- cc) producing a product with component parts that defendant knew or should have known increased the risk of harm to the user;
- dd) supplying a product which was defective and could cause injury to the user;



- ee) engaging in other acts regarding the harvesting, extracting, manufacturing, designing, preparing, producing, distributing, advising and selling of human tissue as will be learned in discovery.
- ff) failing to employ and adhere to a comprehensive and adequate BioCleanse® or similar process or combination of chemical, temperature, and pressure-related safeguards to ensure the safety of its products.

63. As a result of Defendants' violation of the New Jersey's Products Liability Act, Plaintiff was caused to sustain serious emotional and physical harms.

WHEREFORE, Plaintiff Arlene Sechtin, on behalf of herself and all others similarly situated, claim of Defendants, compensatory damages, punitive damages, interest and allowable costs of suit.

**COUNT VI – MEDICAL MONITORING**  
**CLASS MEMBERS**

64. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

65. As a direct result of Defendants' actions and omissions, untested and potentially harmful human tissue which could cause premature death in Plaintiff and Plaintiff Class Members was implanted or otherwise utilized in a surgical and medical procedure and human tissue products.

66. By monitoring and testing the affected blood in Plaintiff and Plaintiff Class Members, it can be determined whether they have contracted certain infectious diseases such as HIV, hepatitis, syphilis, and other viral infections.

67. Because such affected human tissue implanted in Plaintiff and Plaintiff Class Members was never properly screened or tested for such infectious diseases as required by the FDA, medical monitoring is the most appropriate method by which it can be determined whether a particular individual has contracted and otherwise obtained such infectious disease.

68. Accordingly, RTIX and BTS should be required to establish a medical monitoring problem that includes, *inter alia*:

- a. establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of all recipients of affected human tissue, human tissue products, and tissue-related services, as frequently as determined to be medically necessary, as well as to pay development and/or research for other methods by which the risk of those affected by such human tissue can be reduced;
- b. notifying all Plaintiff Class Members in writing, not just notices to Doctors that their human tissue transplant or human tissue product requires frequent medical monitoring; and
- c. providing information to treating physicians to aid them in detecting human tissue and/or human tissue products that may be subject to an increased risk of infectious disease.

69. Plaintiff and Plaintiff Class Members have no adequate remedy at law in that monetary damages alone cannot compensate them for the risk of an infectious disease. Without a Court-approved medical monitoring program as described herein, Plaintiff and the Plaintiff Class Members will continue to face an unreasonable risk of death.

**COUNT VII – PUNITIVE DAMAGES UNDER  
THE NEW JERSEY PUNITIVE DAMAGES ACT**  
(N.J.S.A. § 2A: 15-5.9; § 2A:15-5.12)

70. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

71. Defendants' actions as set forth above were intentional, wanton, willful and outrageous. Defendants were grossly negligent, and acted with reckless disregard of and with deliberate, callous and reckless indifference to the rights, interests, welfare and safety of Plaintiff and all others similarly situated.

72. Defendants' intentional, wanton, willful and outrageous actions consisted of, but are not limited to:

a. intentionally failing to conform to federal regulatory and statutory guidelines related to the extracting, processing, distributing, testing, and safety of human tissue and human tissue related products and/or services, including but not limited to reviewing donor's medical history and other factors, physically assessing the donor and source of tissue, and testing for relevant communicable diseases.

b. intentionally failing to disclose that various human tissue was subject to an increased risk of infectious disease and other harms;

73. By reason of the wanton, willful and outrageous conduct of Defendants, as aforesaid, Plaintiff and all others similarly situated, were caused to sustain said physical and emotional injuries and harms.

74. By reason of the wanton, willful and outrageous conduct of Defendants pursuant to the Restatement of Torts, § 908(1) and the New Jersey Punitive Damages Act, N.J.S.A. § 2A: 15-5.9; § 2A:15-5.12, Defendants are liable for punitive damages and relief as this Court deems just.

*WHEREFORE*, Plaintiff Arlene Sechtin, on behalf of herself and all others similarly situated, claim of Defendants, compensatory damages, punitive damages, interest and allowable costs of suit.

BY: 

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**DATED: JANUARY 9, 2006**

**JURY TRIAL DEMANDED**

Please take notice that the Plaintiff, on behalf of herself and all others similarly situated, hereby demands a trial by jury as to all issues in the above matter.

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**DATED: JANUARY 9, 2006**